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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,508	10/12/2000	Scott A. Ruddell	DI-5654	9098

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EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/689,508	<b>Applicant(s)</b> RUDELL ET AL.	
	<b>Examiner</b> Ann Y. Lam	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29,31-35,44-48,50-58,60,61,99-101,103-108,110-113 and 115 is/are allowed.
- 6) ☒ Claim(s) 1-8,10-16,18,20-28,38-43,62-66,68-71,73 and 95-97 is/are rejected.
- 7) ☒ Claim(s) 17 and 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims pending in the application are 1-8,10-29,31-35,38-58,60-66,68-71,73,95-97,99  
101,103-108,110-113 and 115.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 3-8, 10-16, 18 and 20-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Clayman et al., 6,656,146.

As to claim 1, Clayman discloses a tube (510, figure 5A)) having an implantable portion (512 and *distal* portion of “upper segment”, figure 5A, column 6, line 61) extending from an external patient portion (i.e., portion of tube proximal to implantable portion, including the *proximal* portion of “upper segment” column 6, line 61), the implantable portion having a curved segment (512, column 6, lines 32-34) and a substantially straight section (distal portion of “upper segment”, column 6, lines 60-61) between the external patient portion and a distal end of the implantable portion; a first lumen (main lumen, column 3, line 37) extending through the tube from a first lumen port in the external patient portion to a first lumen port (openings, see figure 5A and also column 5, lines 4-9) in the curved segment of the implantable portion; and a second lumen (bladder lumen, column 3, line 38) extending through the tube from a second

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lumen port (openings, see figure 5A and also column 5, lines 4-9) in the external patient portion to a second lumen port in the implantable portion, the second lumen port (i.e., an opening along the tubular segment that is spaced away from curved segment 512, column 5, lines 9-10) in the implantable portion being spaced away from the curved segment.

As to claim 3, the first lumen port in the curved segment comprises a plurality of openings (column 5, lines 4-5, and see figure 5A) at an outer radial surface of the curved segment.

As to claims 4, 7 and 10, the plurality of openings are substantially round holes, see Figure 5A.

As to claims 5, 8 and 11, the plurality of openings are considered slots, see Figure 5A.

As to claim 6, the implantable portion (512) has a coiled shape at the distal end, see Figure 5A.

As to claim 12, the tube is a single tube having a septum between the first and second lumens, (figure 5A, and column 3, lines 35-37.)

As to claim 13, the first lumen port in the curved segment is capable of being a patient inflow port, (column 3, lines 4-5, and figure 5A.)

As to claim 14, the second lumen port in the implantable portion is a patient outflow port, (column 3, lines 4-5.)

As to claim 15, the first lumen terminates prior to the distal end of the implantable portion, (column 3, lines 35-38.) (Clayman teaches that "at least the bladder end region

of the tubular segment may include two lumens”, thereby indicating that the bladder end region need not have two lumens.)

As to claim 16, Clayman discloses a **connection section** (i.e., *proximal* portion of “upper segment”, figure 5A, column 6, line 61) having an inflow port (openings, see figure 5A and also column 5, lines 4-9; the port is capable of permitting inflow) to a patient inflow lumen, and an outflow port (any of the other openings, see figure 5A and also column 5, lines 4-9; the port is capable of permitting outflow) to a patient outflow lumen; a **patient inflow section** (distal portion of “upper segment”, figure 5A, column 6, line 61) extending from the connection section and having a patient inflow opening (openings, see figure 5A and also column 5, lines 4-9) to the patient inflow lumen; a **separation section** (i.e., proximal portion of 512) extending from the patient inflow section; and a **patient outflow section** (i.e., distal portion of 512) extending from the separation section and having a patient outflow opening (openings, see figure 5A and also column 5, lines 4-9) to the patient outflow lumen wherein the patient inflow section is located closer to a position on the connection section that is suitable for attachment to a patient’s body than to the patient outflow section.

As to claim 18, the patient outflow section (distal portion of 512) is coiled (figure 5A).

As to claim 20, the patient inflow section is considered an uppermost portion of an implantable portion of the catheter and the patient outflow section is considered a lowermost portion of the implantable portion of the catheter.

As to claim 21, the connection section, patient inflow section, separation section, and patient outflow section further comprise a flexible tube having an internal septum between the patient inflow and outflow lumens (column 3, lines 36-39.)

As to claim 22, the connection section and patient inflow section are both portions of (512), the separation section and patient outflow sections are both portions of "upper segment" described in column 6, line 61.

As to claims 23 and 40, the patient inflow opening to the patient inflow lumen is in a direction away from the patient outflow opening to the patient outflow lumen.

As to claims 24, 41 and 42, the catheter comprises a single tube having the patient inflow and outflow lumens, and wherein the tube transitions from having both the patient inflow and outflow lumens to having only the patient outflow lumen at a location between the patient inflow section and a distal catheter end (column 3, lines 35-38; Clayman teaches that "at least the bladder end region of the tubular segment may include two lumens", thereby indicating that the bladder end region need not have two lumens.)

**2.** Claims 25-28, 38-43, 62-66, 68-71, 73 and 95-97 are rejected under 35 U.S.C. 102(b) as being anticipated by Sommercorn et al., 4,543,087

As to claims 25-28, Sommercorn discloses a tube (10) having lumens of differing lengths (see figure 1), the tube having an external patient portion (proximal portion) and implantable portion (distal portion), the lumens having openings as claimed (see figure

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1), and the implantable portion is non-linear in shaped (when it is bent for example, since Applicant has not claimed that the non-linear shape is pre-formed.)

As to claims 38 and 95, Sommercorn discloses a dialysate supply and removal system (column 1, line 6); a catheter (10) connected to the system, the catheter having implantable first and second lumens of differing lengths (see figure 1), the first lumen in a side-by-side arrangement relative to the second lumen (see figure 1), the catheter so positioned and arranged when in use in a peritoneal cavity that fluid flows out of the first lumen in an upper area of the peritoneal cavity and into the second lumen in a lower area of the peritoneal cavity (Column 2, lines 25-27.)

As to claims 39, 40, 63, 64, 65, 68 and 70, the system is automated, and conveys fluid through both lumens (column 1, line 6, column 2, lines 25-27.)

As to claims 41-43, 66, 69, 71, 96 and 97, the catheter is a dual lumen catheter and has different lengths (see figure 1.)

As to claims 62 and 73, openings are found along the catheter as claimed (see figure 1.)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



3. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clayman et al., 6,656,146, in view of Moncrief et al., 5,057,075.

Clayman discloses the invention substantially as claimed, see above. Clayman discloses a ureteral stent for assisting movement of urine along a patient's ureter and into the patient's bladder. However, Clayman does not disclose an implant cuff.

Moncrief et al. discloses a catheter having a cuff (24) that is amenable to in-growth of living tissue, see column 2, lines 19-25, wherein the catheter is to be implanted and used for peritoneal dialysis or for providing access to a particular mechanism of the body such as a circulation system or an internal, artificial or transplanted organ (column 2, lines 13-18.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an implant cuff taught by Moncrief on the Clayman device to allow in-growth of living tissue onto the cuff which is desirable for implanted catheters such as the Clayman catheter, as taught by Moncrief.

#### ***Allowable Subject Matter***

4. Claims 17 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Claims 29, 31-35, 44-48, 50-58, 60, 61, 99-101, 103-108, 110-113 and 115 are allowed.

### ***Response to Arguments***

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Childers et al., 6,497,676, discloses a peritoneal dialysis catheter having dual lumens and a pigtail. Miller et al., 5,683,640, Raulerson, 5,346,471, Gelman, 5,807,329, all disclose a dual lumen catheter. Zabetakis et al., 5,380,298, discloses a catheter for dialysis, having a pigtail.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP ~~1800~~ 1641

6/22/04